Selecting Treatment: Monitoring and Assuring Treatment Fidelity

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Session Plan

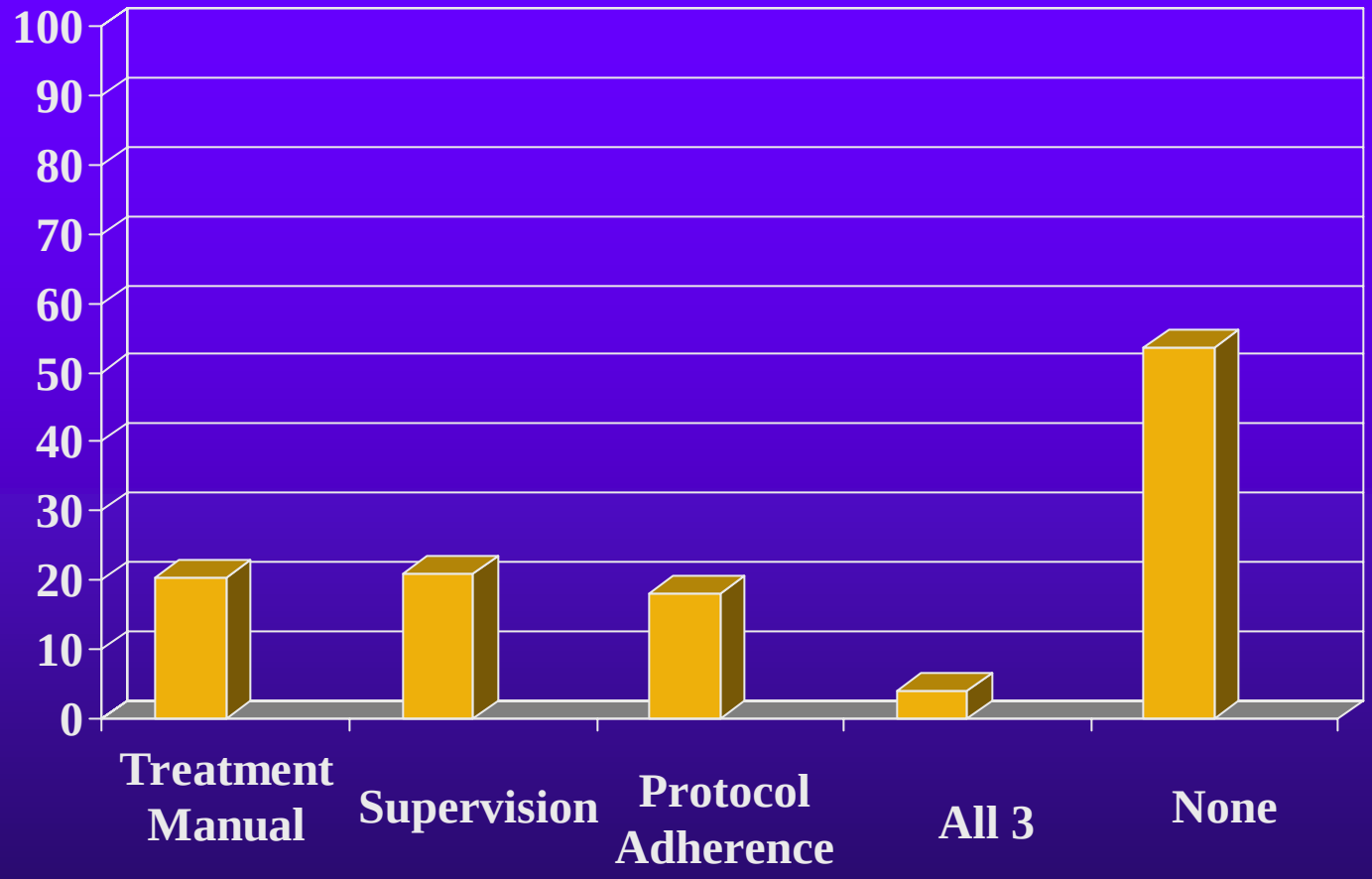
- Treatment fidelity: what is it?
- Why does it matter?
- A treatment implementation model: Induction and Assessment of
  - Treatment delivery
  - Treatment receipt
  - Treatment enactment
- Discussion

2 Aspects of Treatment Fidelity
(Moncher & Prinz, 1991)

- **Treatment integrity**: was the treatment delivered as intended
  - **Conceptually**. Did the developed treatment capture the theoretically active ingredient?
  - **Pragmatically**. Did therapists follow the treatment plan?

- **Treatment differentiation:** did the treatment differ from control condition as intended?
  - **Conceptually.** Were non-specific treatment factors controlled?
  - **Pragmatically.** Did the treatments "bleed?"

Measurement of Treatment Fidelity in the 1980's



Why Does Treatment Fidelity Matter?

- **Preserves internal validity** against
  - **Type I error**: significant treatment effect, but arises because unintended treatment ingredient was added to the intervention
  - **Type II error**: no treatment effect, but treatment wasn't actually administered as intended
- **Improves power** (research efficiency) by reducing unintended variability in treatment effect
- **Supports external validity** by allowing replication, dissemination

A Treatment Implementation Model

(Lichstein et al, 1994)

- **Delivery:** (fidelity) treatment delivered as intended?
  - **Drug:** was prescription written?
  - **Behavioral:** were skills ***taught***?
- **Receipt:** was the treatment received and/or comprehended by the patient?
  - **Drug:** did patient fill prescription?
  - **Behavioral:** did patient ***learn*** skills? Did they understand and can they perform them?
- **Enactment:** (adherence) does patient ***use*** what they received (take drug, practice skills) outside of treatment in daily life?

More about Treatment Implementation

- Delivery, receipt and enactment can be orthogonal
- Analogous to level of treatment penetration
- Conceptualize treatment ***implementation*** as independent of treatment ***outcome***.
  - **adherence (even enactment) ≠ outcome**
    - Adherence to diet and exercise doesn't = or guarantee improvement in bio outcomes like HbA1c, cholesterol, etc.
    - Enactment of skills (relaxation, stimulus control) doesn't even = or guarantee behavioral outcomes like smoking cessation, pain reduction

Induction versus Assessment

- **Induction**
  - Actively doing things to improve treatment implementation
- **Assessment**
  - Monitoring and measuring how well treatment was implemented

Treatment Implementation Model

Induct **Assess**

Delivery

Receipt

Enactment

Treatment Delivery Induction: Getting the treatment delivered as intended

(BCC, Bellg, Borrelli, et al in press)

- Carefully derive the treatment from theory.
  - ⇒What are the intended active treatment ingredients?
  - ⇒What are the target processes/mediators?
    - E.g., Behavior, Cognitions, Motivation
  - ⇒Expert consultation
  - ⇒Specify extraneous active treatment ingredients whose influence needs to be controlled
    - E.g., contact, attention, credibility

Treatment Delivery Induction: Maximizing Fidelity

- **Develop treatment manuals** for the experimental and, if needed, the control treatment

  Except for computerized treatments**, no robots need apply!** Explain theoretical rationale, treatment principles, **utilize clinical judgment!**

- Clear, precise definitions and if/then guidelines
- Per session script integrating goals interventionist/participant roles/materials
- Dosing criteria (e.g., how about prn calls?)

Treatment Delivery Induction: Maximizing Fidelity

- **Centralized training of interventionists**
  - Set criteria and procedures for selecting therapists
  - Anticipate attrition!! Choose and train extra therapists.
  - Model the intervention “live” or via video
  - Role plays with observation
  - Trial with “sample” participant – audiotaped with feedback
  - Trial run at site
  - A priori performance criteria

Treatment Delivery Maintenance Induction

- Supervise therapists
  - Do therapists *understand* the intervention?
- Protocol adherence checklists
  - Topics covered, time spent
  - A priori performance criteria
- Training booster sessions – guard against drift

Treatment Delivery: Assessment

- Direct observation, videotapes, audiotapes, session/process notes
- Best if random rather than fixed assessment schedule
- Monitor multiple “channels:” content, style
- Assess degree and acceptability of tailoring across sites, demographic subgroups
- Ideal: Assess therapist characteristics (gender, age, training, warmth, treatment allegiance)

Treatment Delivery Maintenance Assessment

- Over time
  - Assess stability, watch for drift
  - Check for omission of required elements
  - Check for inclusion of unintended elements
- Between treatment conditions
  - Watch for bleeding/contamination across treatments
  - Hardest when same therapists deliver both interventions
  - Watch for “treatment delivery” by patients in different intervention arms (especially household members)

Tx Receipt Induction: Getting the treatment to be received and/or comprehended by the patient

- **Patient selection**
  - Do they have the target problem?
  - IQ, education, dementia-free
  - Psychological mindedness
  - Willingness to be randomized to either condition
- **In session rehearsal**
- **Clarity/complexity of delivery** (reading level, cartoons, repetition)
- **Tools (handouts, tapes, websites)**

Treatment Receipt Induction

- **Heighten incentives for treatment attendance**
- **Remove access barriers** (childcare, telephone delivery, transportation, web-based or e-mail treatment, take treatment to community)
- **Lower treatment burden** (minimalist interventions, tailored mailings, media, billboard)

Treatment Receipt Assessment

- Session attendance
- Acquisition of supplied treatment tools (meal replacements, pedometer, exercise equipment)
- Pre-post knowledge tests
- Observer rating
- Within-session physiological monitoring
- Self-report of confidence in applying skills
- Completion of homework exercises
- Self-reported reading of tailored mailings, media exposure)

Treatment Enactment Induction: Getting patients to apply what they learned in treatment

- Environmental prompts
- Goal setting
- Treatment contracts
- Contingencies/rewards
- Problem-solving about enactment barriers
- Self-monitoring
- Social support

Treatment Enactment Assessment

- **Direct measurement** (MEMS caps, heart rate monitor, accelerometer, drug blood level, dietary metabolite, gym visits, website hits)
- **Collateral report** (spouse, roommate)
- **Written logs** (food and activity diaries, pack wraps, skill rehearsal log)
- **Retrospective self-report** – 24 hour recall, PDA
  - Best if ***short interval*** and ***unpredictable***